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10/668,274	09/24/2003	Andy Wolff	26486	3490

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Martin D. Moynihan
PRTSI, Inc.
P. O. Box 16446
Arlington, VA 22215

EXAMINER	
CORRIGAN, JAIME W	
ART UNIT	**PAPER NUMBER**
3767	

DATE MAILED: 07/05/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/668,274	WOLFF ET AL.	
	Examiner	Art Unit	
	Jaime W. Corrigan	3767	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-110* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-7,9-11,15,17-34,36-42,44-69,71-78,80-97,99-106 and 108-110* is/are rejected.

7)☒ Claim(s) *8,16,35,43,70,79,98 and 107* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *5-26-04, 7-23-04*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-7, 9-11, 15, 17, 19-34, 36-38, 42, 44, 46-69, 71-74, 78, 80, 82-97, 99-102, 106, 108, 110 are rejected under 35 U.S.C. 102(b) as being anticipated by Hanover et al. (PN 5,196,002).

Regarding claims 1, 28, 55, 83 Hanover et al. discloses a reservoir (See Figure 6 (336)) containing a drug (See Abstract, Column 5 Lines 34-42); and an electronic (See Abstract, Column 3 Lines 53-68, Column 4 Lines 1-9, Column 5 Lines 43-60) drug release mechanism (See Figure 6), for providing said controlled drug release, the device being adapted for insertion to an oral (See Column 1 Lines 14-45) cavity of a subject.

Regarding claims 2, 29, 65, 93 Hanover et al. discloses a control unit (See Column 2 Lines 3-7, Column 3 Lines 53-63), for controlling said controlled release; an electro-mechanical release mechanism (See Figure 6, Column 3 Lines 53-68, Column 4 Lines 1-9, Column 5 Lines 43-60), which opens to allow the release of said drug, responsive to commands from said control unit; and a power source (See Figure 6,

Column 3 Lines 53-68, Column 4 Lines 1-9, Column 5 Lines 43-60), for powering said control unit and electromechanical release mechanism.

Regarding claims 3, 30, 66, 94 Hanover et al. discloses said control unit is selected from the group consisting of a dedicated electronic circuitry (See Figure 6, Column 3 Lines 53-68, Column 4 Lines 1-9, Column 5 Lines 43-60), a processor, an ASIC, and a microcomputer.

Regarding claims 4, 31, 67, 95 Hanover et al. discloses said device for controlled drug release further includes a timing device, selected from the group consisting of a timer, a clock, a calendar, and a combination thereof (See Figure 6, Column 3 Lines 53-68, Column 4 Lines 1-9, Column 5 Lines 43-60).

Regarding claims 5, 32, 68, 96 Hanover et al. discloses at least one local sensor (See Figure 6, Column 3 Lines 53-68, Column 4 Lines 1-9, Column 5 Lines 43-60), integrated with said device.

Regarding claims 6, 33, 73, 101 Hanover et al. discloses at least two local sensors (See Figure 6, Column 3 Lines 53-68, Column 4 Lines 1-9, Column 5 Lines 43-60), integrated with said device.

Regarding claims 7, 34, 69, 97 Hanover et al. discloses said at least one local sensor is a physiological sensor (See Figure 7 (364)), for drug release responsive to measurements of said sensor.

Regarding claims 9, 36, 71, 99 Hanover et al. discloses at least one local sensor is a status sensor, for ensuring that the device is in proper operating condition (See Figure 7 (364)).

Regarding claims 10, 37, 72, 100 Hanover et al. discloses said local status sensor is selected from the group consisting of a sensor for remaining drug in the drug reservoir, a sensor for drug flow rate, a sensor for power source condition, and a sensor for short-circuit detection (See Figure 6 (352)).

Regarding claims 11, 38, 74, 102 Hanover et al. discloses at least one communication component, selected from the group consisting of a receiver, a transmitter, and a transceiver (See Figure 6, Column 3 Lines 53-68, Column 4 Lines 1-9, 17-28, Column 5 Lines 43-60).

Regarding claims 15, 42, 78, 106 Hanover et al. discloses said communication component provides communication with at least one remote sensor (See Column 3 Lines 53-63).

Regarding claims 17, 44, 80, 108 Hanover et al. discloses said device further includes at least one drug-transfer component for increased drug transfer through a biological barrier, by a process selected from the group consisting of iontophoresis, electroosmosis, electrophoresis, electroporation (See Abstract), sonophoresis, and ablation (See Figure 6, Column 3 Lines 53-68, Column 4 Lines 1-9, 17-28, Column 5 Lines 43-60).

Regarding claims 20, 82, 110 Hanover et al. discloses said drug is in nano-size particles (See Abstract, Column 5 Lines 34-42).

Regarding claims 21, 48 Hanover et al. discloses said device is mounted on a dental implement,designed for the oral cavity of the subject (See Figures 6-7).

Regarding claims 22, 49, 56, 84 Hanover et al. discloses said dental implement is selected from the group consisitng of a prosthetic tooth crown, a dental bridge, a dental three-unit bridge, dental implant, partial dentures, full dentures, braces, a molar band, a night guard, and a mouth guard (See Figures 6-7, Column 1 Lines 14-30).

Regarding claims 23, 50 Hanover et al. discloses said device is mounted on an anchor (See Figure 7 (348)) that may be secured to the oral mucosa or the jawbone.

Regarding claims 24, 51 Hanover et al. discloses said device is anchor-free, and is directly implanted into a tissue (See Figures 6-7, Column 1 Lines 14- 60).

Regarding claims 25, 52, 57, 85 Hanover et al. discloses said device is adapted to be removably inserted to the oral cavity of the subject (See Figures 6-7, Column 1 Lines 14- 60).

Regarding claims 26, 53, 58, 86 Hanover et al. discloses said device is adapted to be permanently inserted to the oral cavity of the subject (See Figures 6-7, Column 1 Lines 14- 60).

Regarding claims 27, 54, 59, 87 Hanover et al. discloses said device is adapted to be permanently inserted to the oral cavity of the subject, and said device further includes a removable component, which houses at least one of said drug reservoir (See Figure 6 (336)) and said power (See Figure 6 (344)) source.

Regarding claims 60, 88 Hanover et al. discloses said drug reservoir contains a drug is a dosage form for passive, controlled drug release (See Abstract).

Regarding claims 61, 89 Hanover et al. discloses said drug reservoir contains a drug is a dosage form of nano-size particles (See Abstract, Column 5 Lines 34-42).

Regarding claims 62, 90 Hanover et al. discloses an electronic drug release mechanism (See Abstract, Column 3 Lines 53-68, Column 4 Lines 1-9, Column 5 Lines 43-60).

Regarding claims 63, 91 Hanover et al. discloses said drug is in a controlled release dosage form for a combination of electronic and passive controlled release (See Abstract, Column 3 Lines 53-68, Column 4 Lines 1-9, Column 5 Lines 43-60).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 12-14, 18, 39-41, 45, 75-77, 81, 103-105, 109 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hanover et al. (PN 5,196,002) in view of Duhaylongsod (PN 6,127,410).

Hanover et al. discloses the invention as recited in claims 1, 28, 55, 83 above, however, fails to disclose said communication component provides communication with a personal extracorporeal system; said personal extracorporeal system is selected from the group consisting of a remote control unit, a computer system, a telephone, a mobile phone, a palmtop, a PDA, a laptop, and a combination

thereof; personal extracorporeal system is adapted to provide communication between said device and a monitoring center.

Duhaylongsod teaches that it is conventional in the art to utilize said communication component provides communication with a personal extracorporeal system (See Figure 1, 1C); said personal extracorporeal system is selected from the group consisting of a remote control unit (See Figure 1 (14)), a computer system, a telephone, a mobile phone, a palmtop, a PDA, a laptop, and a combination thereof; personal extracorporeal system is adapted to provide communication between said device and a monitoring center (See Figures 1, 1C, Column 20 Lines 65-67, Column 21 Lines 1-19).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to have utilized the communication with an extracorporeal system as taught by Duhaylongsod in the Hanover et al device since it would improve surgery effectiveness.

Claims 19, 46, 64, 92 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hanover et al. (PN 5,196,002).

Hanover et al. discloses one (See Figure 2 (312)) drug reservoir.

Hanover et al. does not disclose expressly the second drug reservoir.

At the time the invention was made, it would have been an obvious matter of design choice to a person of ordinary skill in the art to double the number of drug reservoirs because Applicant has not disclosed that the extra reservoir provides an

advantage, is used for a particular purpose, or solves a stated problem. One of ordinary skill in the art, furthermore, would have expected Applicant's invention to perform equally well with the single reservoir because it would provide adequate amounts of medication.

Therefore, it would have been an obvious matter of design choice to modify Hanover et al. to obtain the invention as specified in claims 19, 46, 64 and 92.

Allowable Subject Matter

Claims 8, 16, 35, 43, 70, 79, 98, 107 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Gonda et al. (PN 5,743,250), Davidson et al. (PN 6,238,491), Biggs (PN 5,755,575) and Dugot (PN 5,738,521), Nickerson et al. (PN 5,292,252), Casper et al. (PN 5,170,801) disclose similar controlled drug release oral devices.

Any inquiry concerning this communication from the Examiner should be directed to Examiner Jaime Corrigan whose telephone number is (571) 272-4858. The Examiner can normally be reached on Monday – Friday from 8:30 a.m. – 6:00 p.m. 2nd Friday off.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Kevin C. Sirmons, can be reached on (571) 272-4965. The fax number for this group is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (571) 272-3700.

JC

Jaime Corrigan

Patent Examiner
Art Unit 3767

June 13, 2006

KEVIN C. SIRMONS
SUPERVISORY PATENT EXAMINER